

EPA REGISTRATION NUMBER 73079-12 – VOL. 2



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460**

**OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION**

October 3, 2017

Todd J. Fleischmann
Chemical Regulatory Manager
Rockwell Labs Ltd/SiliCide
1257 Bedford Avenue
North Kansas City, MO 64116

Subject: Condition of Registration – Storage Stability and Corrosion Characteristics Data Review
Product Name: SiliCide
EPA Registration Number: 73079-12
Application Date: May 4, 2017
Decision Number: 530379

Dear Todd:

The Agency has reviewed the study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study has been classified as acceptable. The condition of registration is considered fulfilled.

If you have any questions, please contact Matthew Sellner by phone at 703-347-8034, or via email at sellner.matthew@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "R. Gebken", is positioned above the typed name.

Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Registration Division (7505P)
Office of Pesticide Programs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

Date Out: September 18, 2017

~~DOCUMENT CONTAINS CONFIDENTIAL INFORMATION~~

SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS (830.6320) REVIEW
ACCELERATED STUDY ☐; ONE YEAR STUDY ☒; OVER 1 YEAR STUDY ☐ MP ☐ EP ☒ EUP ☐

DP Bar Code: 440740

EPA Reg. No: 73079-12

MIRD: 50275501

Company Name: ROCKWELL LABORATORIES, LTD.

Action Code: 570

Decision No. 530379

End Use Product: "Silicide™"

PCC: 072605

FROM: William Herald, Microbiologist (MS) /Chemist, NEHA/RHES/Registered Sanitarian
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch (CITAB) RD (7505P)
TO: Matthew Sellner / Richard Gebken, RM 10
Invertebrate and Vertebrate Branch 2/ RD (7505P)

Matthew Herald
SR
9/18/17

I. CONCLUSIONS:

STORAGE STABILITY (830.6317):

☒ ACCEPTABLE

☐ UNACCEPTABLE*

☐ UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):

☒ ACCEPTABLE

☐ UNACCEPTABLE*

☐ UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendation

**SUBJECT: STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS (830.6320) REVIEW
ACCELERATED STUDY [] ; ONE YEAR STUDY [X]; OVER 1 YEAR STUDY [] MP [] EP [X] EUP []
DP Bar Code: 440740 EPA Reg. No: 73079-12 MIRD: 50275501
Company Name: ROCKWELL LABORATORIES, LTD. Action Code: 570 Decision No.530379
End Use Product: "Silicide™"
PCC: 072605**

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

B. PRODUCT INFORMATION

Active ingredient(s): Silicone Dioxide

Label claims Nominal concentration(%): 92.1%

Initial concentration(s) of the AI(s) (%) used in the study: 90.27%

Lower certified limits (%) based on AI % in the study: 87.56%

C. EXPERIMENTAL PARAMETERS

Temperature: 55°F to 90°F.

Humidity: Not given

Duration of study: 12 months.

Type of container: High Density Polyethylene (HDPE) plastic bottles.

Analysis at intervals: 0 (initial) and 17 months

D. ANALYTICAL METHOD

Method	DETECTOR
Heated to drive off bound water	Scale

E. RESULTS

The reported results show that the concentration of the active ingredient remained well within certified limits and remained a white dust while stored under ambient warehouse conditions throughout the 12 month study period. No reactions were observed between the test substance and the containers; there were no changes reported in the HDPE plastic bottles throughout the 12-month study period.



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 73079-12	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rockwell Labs Ltd/SiliCide(TM)	PM# 10	
5. Name and Address of Applicant (Include ZIP Code) 1257 Bedford Avenue North Kansas City, MO 64116 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

One year Storage Stability (830.6317) and Corrosion Characteristic (830.6320) Data in support of the unconditional registration of SiliCide (TM). Updated study to reflect new enforcement analytical method requested by US EPA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2, 4, 8 oz, 5 lb		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Todd J. Fleischmann	Title Chemical Regulatory Mgr.	Telephone No. (Include Area Code) (816) 268 5639
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature <i>Todd J. Fleischmann</i>	3. Title Chemical Regulatory Manager	
4. Typed Name Todd J. Fleischmann	5. Date 5/4/2017	

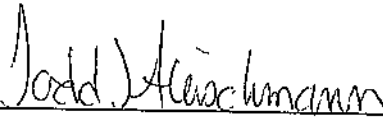
TRANSMITTAL DOCUMENT

Submitter:

Rockwell Labs Ltd
1257 Bedford Avenue
North Kansas City, MO 64116

EPA No. 73079

Company Contact:



Typed Name of Signer: Todd J. Fleischmann

Phone: (816) 268 5635

Fax: (816) 283 3173

Email address: toddf@rockwelllabs.com

Regulatory Action in Support of Which this Package is Submitted:

EPA Registration No.: 73079-12, SiliCide™

One year Storage Stability and Corrosion Characteristic Study
submission.

50275501

Submission date: May 4, 2017

List of Submitted Documents:

Volume 1—Storage Stability and Corrosion Characteristics Study

Receipt for Section 3

S: 1003296

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Company: 73079 ROCKWELL LABS LTD

Billable: ☒ Yes ☐ No

V

Risk Manager: Registration Division, Risk Management Team 10

Print Letter

Enter More Information

Tracking

Product #: 73079-12 Product Name: SILICIDE(TM)

Override:

Me Too

Section 3

71788-1

Me Too Product

Name:

DRI-OUT INSECTICIDE

...

Application Date: 22-Apr-2017

OPP Recvd Date: 09-May-2017

Front End Date: 09-May-2017

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content		Des
Study		
<input type="text" value="111"/>		

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

View/Edit

Cond data as requested by the Agency

New Ingredient

Request Date

New Ingredient

Received Date

Form A: ☐

Signature Date

Form B: ☐

Signature Date



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 30, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ROCKWELL LABS LTD
1257 BEDFORD AVENUE
NORTH KANSAS CITY, MO 64116

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 09-MAY-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

April 22, 2017

Richard Gebken
U.S. Environmental Protection Agency
Document Processing Desk
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

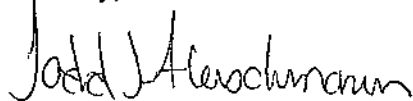
Re: SiliCide™, EPA No. 73079-12
Updated Storage Stability and Corrosion Characteristics Study

Dear Mr. Gebken,

Enclosed is three copies of a new one year Storage Stability and Corrosion Characteristic study to accompany the product chemistry studies and enforcement analytical method requested by US EPA in 2015 for SiliCide™. EPA requested these studies in order to provide a more detailed description of the contents of the product. As such we voluntarily decided to also redo the SSCC study in order to comply with the new analytical enforcement method and are submitting it for your records.

Thank you in advance for your kind attention. Should you have any questions or comments please contact me at 816-268-5635 or by email at toddj@rockwelllabs.com.

Sincerely,



Todd J. Fleischmann
Chemical Regulatory Manager

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PROCESSING REQUEST

Reg # 7307 Decision # 513178

Description: new CSF

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 4/19/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: L. DeLuise

Division: RD

Phone: 305-5428

Date: 6/2/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 1, 2016

Ms. Cisse W. Spragins, PhD
Rockwell Labs Ltd
1257 Bedford Avenue
North Kansas City, MO 64116

Subject: PRIA Label and CSF Amendment –Providing chemistry data to support this product and changing Ingredient Statement for silicon dioxide
Product Name: Silicide™
EPA Registration Number: 73079-12
Application Date: January 4, 2016
Decision Number: 513178

Dear Dr. Spragins:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Please note that the record for this product currently contains the following CSF:

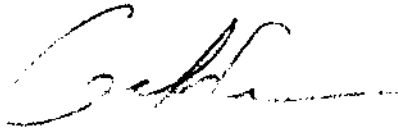
- Basic CSF dated 04/19/2016

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false

or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Linda A. DeLuise by phone at 703-305-5428, or via email at deluise.linda@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Richard Gebken', with a long horizontal flourish extending to the right.

Richard Gebken
Product Manager 10
Invertebrate & Vertebrate Branch 2
Office of Pesticide Programs

Enclosure

SiliCide™

ABN: CimeXa™ Insecticide Dust

ABN: Maggie's Farm™ Simply Effective™ Bed Bug Killer

Active Ingredient: Silicon Dioxide as Amorphous Silica.....92.1%
Other Ingredients.....7.9%
Total:.....100.0%

EPA Reg. No.: 73079-12

EPA Est. No.: (as applicable)

Net Contents: 2 oz, 3 oz, 4 oz, 8 oz, 1 lb, 2 lbs, 5 lbs, 10 lbs

KEEP OUT OF REACH OF CHILDREN
CAUTION

ACCEPTED

06/01/2016

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 73079-12

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals: CAUTION: Causes moderate eye irritation.

Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use Restrictions: In edible product areas of food handling establishments, restaurants or other areas where food is commercially prepared or processed, or in serving areas when food is exposed, this product may only be applied as a crack and crevice treatment. Any product remaining outside of cracks and crevices must be cleaned up and removed.

Application Directions

Use Sites: In and around residential, multi-family, commercial, industrial, institutional, municipal, agricultural, research, daycare, health care, educational, recreational, and office buildings, hotels, motels, garages, transport vehicles, warehouses, theaters, and other manmade structures, and food handling and food processing establishments.

General Information: SiliCide™ is a desiccant dust that has no odor and will not stain. When pests contact SiliCide™, the product clings to their exoskeleton and absorbs the waxy coating, causing death from dehydration.

Application Rates and Methods: Apply at a rate of 2 ounces per 100 square feet. In attics and crawlspaces, apply at a rate of 1 lb per 1000 square feet. Use a handheld bellows, bulb or puffer bottle type duster to apply a light, visible film. A craft or paint brush is useful for pushing dust into cracks and crevices, and into tufts and folds of mattresses and cushions. A power duster may also be used. **Power duster use is limited to cracks, crevices, voids, attics and crawlspaces to insure containment of dust particles.** Liquid Application: The product may be used as a spray, paint on application, or foam. Combine up to 1 lb of product with 1 gallon of clean water. Apply approximately 1 quart of product/water slurry per 250 square feet of area to be treated. The product does not dissolve in water and will be left behind and visible after evaporation. For injection treatment, add the appropriate amount of foaming agent to the product/water slurry and inject directly into galleries and voids.

General Pest (Ants, Cockroaches, Firebrats, Silverfish, Spiders, Mites) Treatment: Treat attics, crawl spaces, trash closets, utility closets, behind baseboards, around the perimeter of dropped ceilings, in hollow furniture legs; under and behind bedding, appliances and vending machines; in wall voids and voids under and behind cabinets, sinks and tubs; in drawer wells, garbage chutes, pipe chases, weep holes in brick or siding, elevator pits, around drains, around electrical conduits and in cracks and crevices where insects may harbor. Focus application in areas where insects or their signs are seen.

Application tips for certain use sites follow:

1. In attics, be sure to get dust near the eaves and vent pipes where insects often first enter, as well as around any pipes or potential access points between the attic and the main structure.
2. When treating cabinetry areas, if there is no gap between the lower cabinets and the kickplate, then small holes can be drilled to access the voids. Escutcheon plates around pipes can also be pulled back to allow access to voids.
3. The bottom drawers in kitchen and bathroom cabinets can be removed and dust applied into drawer wells. No dust should be left exposed when drawers are replaced.
4. Electrical switch plate covers can be removed to allow access to voids, but dust shouldn't be applied directly in electrical boxes.
5. If there are cracks between baseboards, cabinets, doorframes, hinges, counters or trim, and walls, these cracks can be lightly dusted with product. If practical, these areas can be sealed once insect problems have been eliminated, to help prevent future problems.
6. Insects need moisture, so kitchen and bath areas and areas immediately surrounding them, and any other damp areas should be carefully inspected and treated if necessary.

Bed Bug Treatment: Remove bedding and take the bed apart. Treat the interior framework, joints and cracks in the bed frame. Treat the mattress and box spring, paying particular attention to tufts, folds and edges, and the interior framework of the box spring.

Remove wall-mounted head boards and treat the back side. Treat picture frames, moldings, hollow furniture legs, cracks and crevices, along baseboards, and any areas with visible signs of infestation, including rugs and carpet. Treat upholstered furniture by removing or lifting (if possible) the cushions and treating the undersurface. Treat the interior framework, cracks and joints of the furniture, and the folds, tufts and edges of cushions and other upholstered areas. Do not treat toys and stuffed animals with product. Treat wall voids by removing electrical switch plate covers to allow access, but don't apply dust directly in electrical boxes. Apply about ¼ oz of dust to each accessible void.

Flea, Lice and Tick Treatment: Treat kennels, pet bedding/rest areas, floor and floor coverings, cracks behind molding and baseboards and other areas where pests may harbor.

Stored Product (Pantry and Fabric/Clothes) Beetles and Moths: Treat cracks, crevices and along the edges of cupboards, closets, pantries, shelving units and storage. Treat voids beneath drawer units by removing the lower drawers and treating the well. Treat the voids beneath shelving units or cabinets by removing the kickplate or drilling small access holes in the kickplate. Treat under rugs and along the edges of carpets and baseboards and other infested areas to control carpet beetles.

Drywood Termite Treatment: For existing infestations of drywood termites, use a drill or probe to locate and access galleries and inject product directly into galleries. An electric or pneumatic duster which produces a pressure of at least 30 psi and no more than 175 psi should be used to force dust throughout galleries. Any holes left in framing covering must be closed and sealed.

Drywood Termite Prevention: Apply at a rate of 1 lb per 1000 square feet in attics and crawlspaces so that the product coats wood members. Drill periodic access holes into wall and ceiling voids and inject the dust at a rate of 1 lb per 1000 square feet of surface area. Insure sufficient holes are drilled to cover interior framing in voids. The working pressure range of electric or pneumatic dusters should be from 30 to 175 psi and the air supply should be dried if the relative humidity is higher than 50%.

Food Processing and Handling Establishment Application, including Federally-Inspected Meat and Poultry Plants: In food areas, only apply dusts in cracks, crevices, and other inaccessible areas. Avoid contamination of food and feedstuffs. Avoid introducing the product into the air. Never apply powder directly to a surface where food is stored, prepared or served. Any dust that is left visible after treatment should be removed and the exposed surface washed. Food areas include: processing areas, including enclosed systems such as syrup and oil plants, dairies, and mills; packing areas, including bottling, canning, wrapping and boxing; receiving areas; storage areas, including edible waste storage; and serving areas, such as dining rooms. In these areas, dust sparingly into cracks and crevices, such as along baseboards and between construction elements. Do not apply in serving areas when facility is in operation or when food is exposed. Do not treat surfaces likely to be contacted by food.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a dry place. Do not store where children or animals may gain access.

Disposal: If Empty: Non-refillable container. Do not reuse this container. Place in trash or offer for recycling if available. **If Partly Filled:** Call your local solid waste agency or 1-800-CLEANUP which is managed as a public-private partnership.

[Warranty Limitations and Disclaimer

Seller makes no warranty expressed or implied, concerning the use of this product other than as indicated on the label. Buyer accepts this material subject to these terms, and assumes all risk of usage and handling except when used or handled in accordance with this label. There are no expressed or implied warranties of merchantability or fitness for any particular purpose, except as specifically stated herein. To the extent consistent with applicable law, the manufacturer shall not be liable for any consequential damages based on the use of the product.]

Manufactured by: Rockwell Labs Ltd [logo]
 1257 Bedford Ave
 [North] Kansas City, MO 64116
[Phone number] [www.rockwelllabs.com/www.maggiesfarmproducts.com]

[© XXXX] [Trademark(s) ownership statement]
[Green Zone is not a third party certification.] *Used when Green Zone Brand logo is used.*

NOTE: ***Bold italicized text is information for the reader and not part of the label.***
[Bracketed information is optional text.] Text separated by / denotes and / or options.

Page 5 of 5

Marketing Claims

[Dust] For Control of/Kills: Ants, Cockroaches, Firebrats, Silverfish, Spiders, Mites, Bed Bugs, Lice, Fleas, Ticks, Stored Product/Pantry/Fabric/Clothes Beetles and Moths and Drywood Termites

[Kills Bed Bug Adults and Nymphs]
[Kills Bed Bug Nymphs Hatched from Dusted Eggs]
[Kills Pyrethroid-Resistant Bed Bugs]
[Provides Fast Control]
[Lasts Up to Ten Years When Undisturbed]
[Odorless]
[Non-Staining]

[WBE Woman Business Enterprise NWBOC Certified (logo)] ***As factual based on company certification***

[Green Zone Brand [(logo)]]

Logo options depicted below in grayscale – may be colorized in actual use





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

FILE

- Contains Confidential Business Information -

DP BARCODE Nos.: 432485, 432850; FILE SYMBOL No.: 73079-12; PRODUCT NAME: Silicide™;
DECISION No.: 513178; PC Code: 072605; ACTION CODE: R340; FOOD Use: NO

DATE OUT: April 19, 2016

SUBJECT: End Use Product Chemistry Review
- Unregistered Source of Active Ingredient
Product Name: Silicide™

FROM: María I. Rodríguez, Chemist
Product Chemistry Reviewer
CITAB/RD (7505P)

María I. Rodríguez
April 19, 2016

THROUGH: Shyam Mathur, Ph. D.
Product Chemistry Team Leader
CITAB/RD (7505P)

SBM 4/21/16

TO: Linda DeLuise/Richard Gebken, RM #10
IVB#2/RD (7505P)

INTRODUCTION:

The registrant has submitted an application for the registration of the new end use product Silicide. Silicon dioxide as amorphous silica is the technical active ingredient in the formulation. The source of this active ingredient is not registered. The registrant has submitted a Confidential Statement of Formula (CSF) for the Basic formulation dated April 9, 2016. Supporting Product Chemistry data with MRID Nos 498078-01 and -02 was also submitted. The Data Matrix is dated February 2, 2016. A completeness check screening was conducted by CITAB (Chemistry – SMathur) on March 31, 2016. At the time the registrant was asked clarify the discrepancy between the nominal concentration of the active ingredient (AI) on the proposed label and the CSF based on the submitted batch analysis data. The registrant has responded to the deficiencies listed on the screen. CITAB (Chemistry) has been asked to determine the acceptability of the proposed CSF and the supporting Product Chemistry data.

NOTE: This review consists of "Report on End-use Product Silicide" (Page 2) and "Report on Unregistered Silicon Dioxide as Amorphous Silica" as Technical Grade Active Ingredient in the Formulation (of Silicide) (Page 6).

REPORT ON END-USE PRODUCT SILICIDE:

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Silicon dioxide (as amorphous silica) (92.1%)
2. Has the registrant claimed substantial similarity to a registered product? ☐ Yes; ☒ No; ☐ NA
3. All of the source materials of the active ingredient are derived from registered sources: ☐ Yes; ☒ No
 - The source of the active ingredient is not registered. There is a R.E.D. dated September 1991 for "Silicon Dioxide and Silica Gel." This review contains a report on unregistered silicon dioxide (as amorphous silica) as a technical grade active ingredient in the formulation of Silicide (on page 6).
4. All inert ingredients have been screened by CITAB (Inerts) and found to be approved for the proposed labeled use(s): ☐ Yes; ☐ No; ☒ NA
 - Technical and impurities only (no inerts to review) in the proposed CSF (JK; January 28, 2016)
5. Confidential Statement of Formula (CSF):
 - ☒ Proposed Basic CSF: Dated: 12-31-2015; Resubmitted: 04-09-2016
 - Original submission dated January 4, 2016
 - The registrant submitted a listing of "different polymorphs of silica along with CAS numbers associated with them. The "general overall" CAS No for "silica" is 7631-86-9 and that for "synthetic amorphous silica manufactured by a [REDACTED] is 112926-00-8. This is the CAS No the registrant is using for their product. OPPIN lists 7631-86-9.
6. Product label:
 - a. Ingredient statement: Nominal concentration of AI listed on CSF concurs with product label (PR Notice 91-2): ☒ Yes; ☐ No

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)
☒ Yes; ☐ No

Metallic equivalent: ☐ Yes; ☐ No; ☒ NA
Soluble arsenic: ☐ Yes; ☐ No; ☒ NA
Isomeric ratios: ☐ Yes; ☐ No; ☒ NA
Acid Equivalent: ☐ Yes; ☐ No; ☒ NA
 - b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA
Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA
Sodium nitrate/Sodium Nitrite: ☐ Yes; ☐ No; ☒ NA
 - c. Physical-chemical hazard statement: Product label requires a statement *per* 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown? ☐ Yes; ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
☐ Yes; ☐ No; ☒ NA
 - d. Label requires an additional Storage and Disposal statement: ☐ Yes; ☒ No

7. Group A: Product Chemistry Data – Product Identity, Composition, and Analysis

- Product Identity, Composition, and Analysis for Silicon Dioxide (as amorphous silica)
 - MRID No 498078-01

Guideline Number	Study Title	Data Submitted		CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
830.1550	Product Identity & Composition		X	A	498078-01
830.1600	Description of materials used to produce the product		X	A	498078-01
830.1650	Description of formulation process		X	A	498078-01
830.1670	Discussion on the formation of impurities		X	A	498078-01
830.1700	Preliminary analysis		----	NA	NA
830.1750	Certified limits (158.350)	Standard certified limits	----	----	498078-01
		Proposed Limits	X	A	Basic CSF 04-09-2016
		Justification for wider limits	----	----	498078-01
830.1800	Enforcement analytical method		X	A	Gravimetry (USP Method for Silicon Dioxide Determination) Not Validated (Verified Published Method)

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable;
 I = In Progress; U = Upgradeable

8. Group B: Product Chemistry Data – Physical and Chemical Characteristics

- Physical and Chemical Characteristics for Silicon Dioxide (as amorphous silica)
 - MRID No 498078-02

Guideline Number	Study Title	Value or Qualitative Description	CITAB's Assessment of CHEMISTRY Data	MRID Number Cited
830.6302	Color	White, opaque	A	498078-02
830.6303	Physical State	Solid, fine powder/dust	A	498078-02
830.6304	Odor	None	A	498078-02
830.6314	Oxidation/reduction	Non-reactive to iron fillings, nitric acid, water, and mineral spirits	A	498078-02
830.6315	Flammability	NA -Non-flammable	NA	498078-02
830.6316	Explosibility	NA -Not shock or thermally explosive	NA	498078-02
830.6317	Storage Stability	Stable	A	MSDS
830.6319	Miscibility	NA -Not an emulsifiable liquid	NA	498078-02
830.6320	Corrosion Characteristics	No Data Available	A	MSDS
830.6321	Dielectric Breakdown Voltage	NA -Not intended to be used around electric equipment	NA	NA
830.7000	pH	6.54 @ 20.5 °C (1% solution)	A	498078-02
830.7100	Viscosity	NA -Solid	NA	498078-02
830.7300	Density/Relative Density/Bulk Density (Specific Gravity)	0.121 g/cm ³ @ 20.5 °C Bulk density (uncompressed)	A	498078-02

A = Acceptable; N = Not Acceptable; G = Data Gap; W = Waiver request; NA = Not applicable;
 I = In Progress; U = Upgradeable

DP BARCODE Nos.: 432485, 432850; **FILE SYMBOL No.:** 73079-12; **PRODUCT NAME:** Silicide™;
DECISION No.: 513178; **PC Code:** 072605; **ACTION CODE:** R340; **FOOD Use:** NO

CONCLUSIONS:

The CITAB (Chemistry) has reviewed this submission and concludes the following:

1. The proposed Basic CSF (04-09-2016) for the proposed end use product is acceptable. It is attached to this review and stamped/signed "acceptable" by the CITAB (Chemistry).
2. The data submitted for Group A Data under the 830 Series are acceptable.
3. The data submitted for Group B Data under the 830 Series are acceptable.

DP BARCODE Nos.: 432485, 432850; FILE SYMBOL No.: 73079-12; PRODUCT NAME: Silicide™;
DECISION No.: 513178; PC Code: 072605; ACTION CODE: R340; FOOD Use: NO

REPORT ON UNREGISTERED SILICONE DIOXIDE AS AMORPHOUS SILICA:

- Technical Grade Active Ingredient in the Formulation of Silicide

SUMMARY OF FINDINGS AND CONCLUSIONS:

1. The registrant submitted Product Chemistry data corresponding to Guideline 830 series Group A and B to support the unregistered active ingredient silicon dioxide (as amorphous silica) produced by [REDACTED]

2. The data satisfies the requirements under 40 CFR §158.345 and §158.355 for preliminary analysis (830.1700) and enforcement analytical method (830.1800), respectively. All the data is deemed acceptable.

Product ingredient source information may be entitled to confidential treatment

